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November 2, 2021

BY ECF & OVERNIGHT MAIL

Honorable Freda L. Wolfson
Chief United States District Judge
U.S. District Court for the District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street Court, Room 5E
Trenton, New Jersey 08608

Re: *Sanofi-Aventis U.S., LLC v. U.S. Department of Health and Human Services, et al.*, Civil Action No. 3:21-cv-634

Dear Chief Judge Wolfson:

Plaintiff Sanofi-Aventis U.S., LLC (“Sanofi”) respectfully notifies the Court that Judge Barker of the U.S. District Court for the Southern District of Indiana issued the enclosed decision on October 29, 2021, in *Eli Lilly and Company, et al. v. U.S. Department of Health and Human Services, et al.*, No. 1:21-cv-0081 (S.D. Ind.). The decision vacated two agency actions: Advisory Opinion 20-06, which Sanofi also challenges in this action, and HRSA’s May 17 letter to Eli Lilly and Company (“Lilly”), which is similar to HRSA’s May 17 letter to Sanofi at issue in this action. In particular, Judge Barker held that the Advisory Opinion was arbitrary and capricious. *Id.* at 34. As for HRSA’s May 17 letter to Lilly, Judge Barker held that it too, although not contrary to law, was arbitrary and capricious. *Id.* at 58. In this case, Sanofi has challenged both the Advisory Opinion and HRSA’s May 17 Letter to Sanofi as contrary to law and arbitrary and capricious.

In light of the ADR Panel’s Initial Scheduling Order, which deferred Sanofi’s deadline to respond to the ADR petition beyond November 5, *see* ECF 106, Sanofi respectfully requests the opportunity to provide the Court with supplemental briefing on Judge Barker’s decision, including its applicability to the unique features of Sanofi’s integrity initiative, *see* ECF 68-1, at 30-33; ECF 94, at 15-17. Sanofi proposes that the parties simultaneously file supplemental briefs limited to five pages on or before November 5.

Sanofi has conferred with the government about supplemental briefing. The government stated that “[w]e do not think it is necessary to provide supplemental briefing on the *Lilly* decision, given the thoroughness of the parties’ existing briefing, and instead intend to file in each docket a short Notice of Supplemental Authority setting forth the government’s position on the impact of that ruling.”

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Respectfully Submitted,

s/ Jennifer L. Del Medico

cc: All counsel of record